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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/242,254 | 05/07/99 | FORSSMANN W | FORSSMANNETA |

HM12/0424

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| EXAMINER | |
|---|---|
| BASKAR, P | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | 14 |

**DATE MAILED:** 04/24/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/242,254 | FORSSMANN ET AL. | |
| | Examiner | Art Unit | |
| | Padmavathi v Baskar | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on *2/12/01* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4-9 and 11-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-9 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

## DETAILED ACTION

1. The request filed on 2/12/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/242,254 is acceptable and a CPA has been established. An action on the CPA follows.

2. Claims 2, 3 and 10 have been canceled. Claims 1, 11-13 have been amended. Claims 1, 4-9 and 11-13 are pending in the application and are under examination.

***Specification - Informalities***

3. This application is informal in the arrangement of the specification. Applicant attention is directed to MPEP 608.01(a).

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

**Arrangement of Specification**

The following order or arrangement is preferred in framing the specification and, except for the title of the invention, each of the lettered items should be preceded by the headings indicated below.

(a) Title of the Invention.

(b) Cross-References to Related Applications (if any).

(c) Statement as to rights to inventions made under Federally sponsored research and development (if any).

(d) Background of the Invention.

1. Field of the Invention
2. Description of the Prior Art.

(e) Summary of the Invention.

(f) Brief Description of the Drawing.

(g) Description of the Preferred Embodiment(s).

(h) Claim(s).

(I) Abstract of the Disclosure.

This application has not followed the directions or order or arrangement in framing the specification as mentioned above. There are no line numbers in pages. And also applicant should insert "What is claimed" before the claims.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 4-9 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting the low molecular weight peptides by so called MALDI method (matrix assisted laser desorption ionization mass spectroscopy, does not reasonably provide enablement for a method for detecting a pathogenic or any other condition of organism from the group consisting of prokaryote, eukaryote, multicellular organism, cells from tissue culture and cells from animals and humans, genetically engineered organism, genetically transformed organism and a conditioned organism .The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims as recited broadly in instant claims.

Instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in In re Wands, 858 F.2d 731,8 USPQ2d 1400 ( Fed.Circ.1988) as follows:

(1) The nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

In the instant case, other than a method for determining the low molecular weight peptides by so called MALDI method (matrix assisted laser desorption ionization mass spectroscopy) from body fluids such as hemofiltrate, ascitic fluid and urine the instant specification is not-enabled a method for detecting a pathogenic or any other condition of organism from the group consisting of prokaryote, eukaryote, multicellular organism, genetically engineered organism, genetically transformed organism, conditioned organism, cells from tissue culture and cells from animals and humans, Specification provides guidance and direction to a method for determining the low molecular weight peptides by so called MALDI method (matrix

assisted laser desorption ionization mass spectroscopy) from body fluids such as hemofiltrate, ascitic fluid and urine (specification: pages 8-15). However, there is no evidence or guidance or direction how to test a pathogenic or any other condition of organism. Further there is no evidence how to correlate and differentiate various conditions of organism as recited in the claims 1, 11-13. The enabling disclosure is clearly not commensurate in scope with these claims. Clearly there is lack of guidance directing a skilled artisan to practice the instantly claimed methods. Without specific guidance or direction and /or working examples, one of ordinary skill in the art would not be able to reproducibly practice the entire scope of the invention as claimed, without undue experimentation.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 1, 4-9 and 11-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps. See MPEP § 2172.01. Applicant claims a method for detecting pathogenic or any other condition of an organism. However, there is no step, which correlates and differentiates the pathogenic or any other condition of said organism. What is detected? What is correlated?

Method claims need not recite all operating details but should be at least recite positive, active steps so that the claim will set out and circumscribe particular areas with a reasonable degree of precision and particularity and make clear what subject matter claims encompass, as well as make clear subject matter from which others would be precluded.

What are the metes and bound of any other condition?

Cells from tissue cultures and cells from animals and humans are not considered organisms.

How does measuring high and low molecular weight peptides indicate the state of the organism (i.e., pathogenic or any other condition) ?

Claim 1 is vague in reciting "wherein the detecting of said low-molecular weight peptides is effected by parameters such as molecular weight". How does detection of low molecular weight peptides effected by parameters such as molecular weight?

Claim 1 is further rejected as being vague and indefinite for the recitation of "low molecular weight peptides used for said measurement " What are these low molecular weight peptides? Are they obtained from virus, bacteria or fungus?

Claim 1 is rejected as being vague in reciting "reference and said reference comprises a distribution of low molecular weight peptides in a representative cross-section of defined controls to produce differential display." What is this reference? This method is to detect pathogenic condition of organism so what are these defined controls?

Claim 4 recites "dipeptides" what are these dipeptides and they correspond to what?

Claim 9 is rejected as being vague in reciting "fractions" and "different conditions" Is said sample being fractionated before starting the said method as recited in claim 1? What are these different conditions?

Applicant argues that the present invention is a general method for identifying the condition of organism, First of all it is totally confusing with respect to what applicant means by organism? Is it an individual? Is it a bacterium? Is it a virus? Is it a parasite? Since this not clear to the examiner then the arguments about the terms "without the need to recur to "condition and "references are not understood. Further examiner is confused of the term "condition." Does this mean good condition or bad condition? Is it a chronic stage of the infection? Is it an acute stage of the infection? Is it a relapse or what?

Finally applicant argues about dipeptide and indicates that they are gly-gly. Applicant is arguing about the limitations, which are not set forth in the claims.

## *Claim Rejections - 35 USC § 102*

8. Rejection of claims 1, 4, 8, 12 and 13 under 35 U.S.C. 102(b) as being anticipated by Harry et al, 1989 (Clinical Microbiology Reviews, Vol 2, pages 241-249) is maintained for essentially the same reasons as the rejections of claims 1-4, 8, 10, 12 and 13 under this statutory provision, as set forth in the last Office action.

Claims are directed to a method for detecting the condition of an organism through the measurement of peptides from a sample containing high and low molecular peptides.

Harry et al disclose a method for detecting HIV p24 antigen by using commercially available capture assays from a sample (see page 241 and Table 1). The prior art anticipates the claimed invention.

Applicants' arguments filed on 212/2001 have been fully considered but they are not deemed to be persuasive.

Applicant argues that the method disclosed by Harry et al directed to protein or fragments and is not relevant for the condition of the organism I whereas the claimed invention is for the analysis of low molecular weight peptides. Examiner disagrees with the applicant because Harry et al□s method also detects the low molecular weight peptides such as p24 and depending on the amount of the p24 antigen, stage of infection could be diagnosed. Since the claimed invention is not clearly recited by the claims and is so broadly written, the prior art anticipates the claimed invention.

In response to applicant's argument that the references fail to show certain features of the disclosed invention, it is noted that the features upon which applicant relies (i.e., peptide function; direct measurement; relevance to individual└F condition) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). And also specification does not teach detectng a pathogenic or any other condition of organism from the group consisting of prokaryote, eukaryote, multicellular organism, cells from tissue culture and cells from animals and humans, genetically engineered organism, genetically transformed organism and a conditioned organism. Further applicant gives examples and how to know the physiological role of peptides in the present 2/12/01 response in pages 7-8. Since there is no teaching of any disease in the specification, this argument is not found persuasive.

9. Rejection of claims 1,4, 8 under 35 U.S.C. 102(b) as being anticipated by Ausubel et al 1995 (Short Protocols In Molecular Biology, Chapter on analysis of proteins) is maintained for essentially the same reasons as the rejections of claims 1-4, 8, 10, 12 and 13 under this statutory provision, as set forth in the last Office action.

Claims are directed to a method for detecting the condition of an organism through the measurement of peptides from a sample containing high and low molecular peptides.

Ausbel et al discloses a number of methods for protein analysis in Chapter 10. For example Immunoaffinity Chromatography, Reversed-Phase high-performance Liquid Chromatography. All these methods are used to detect high and low molecular weight peptides in a sample, (see pages 10-54-10-58; 10-64-10-69). The prior art anticipates the claimed invention.

Applicants' arguments filed on 2/12/2001 have been fully considered but they are not deemed to be persuasive.

Applicant argues that Ausubel does not disclose any method, which detects low molecular weight peptides. Examiner disagrees and again emphasizes that the independent claim 1 is so broad that any method such as the method described by Ausbel would read on the claims. Since the term "condition is not clear, the prior art anticipates the claimed invention

In response to applicant's argument that the references fail to show certain features of disclosed invention, it is noted that the features upon which applicant relies (i.e., condition/status of an individual, references from other organisms; characterization of low molecular weight or dipeptides) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Since there is no teaching of any disease in the specification, this argument is not found persuasive.

10. Rejection of claims 1, 4-9 and 11-13 under 35 U.S.C. 102(b) as being anticipated by Jimenez et al 1994 (Journal of Neurochemistry; Vol. 62; pages 404-407) is maintained for essentially the same reasons as the rejections of claims 1- 13 under this statutory provision, as set forth in the last Office action.

Claims are directed to a method for detecting the condition of an organism through the measurement of peptides from a sample containing high and low molecular peptides by mass spectrometry.

Jimenez et al disclose a method, matrix-assisted laser desorption ionization mass spectrometry (MALDI-MS) technique for identifying neuronal peptides with low molecular weights from snails (see experimental procedures and figure 2 and 3). The prior art anticipates the claimed invention.

Applicants' arguments filed on 2/12/01 have been fully considered but they are not deemed to be persuasive.

Applicant argues that the Jimenez et al does not disclose the claimed invention rather discloses a method, which identifies high molecular weight substances. Further he argues that Jimenez et al□s method does not disclose the condition of organism. Since the term condition is not clear and the claims are broad this prior art applies as it detects low molecular weight peptides. Since there is no teaching of any disease in the specification, this argument is not found persuasive.

***Status of Claims***

11. No claims are allowed.

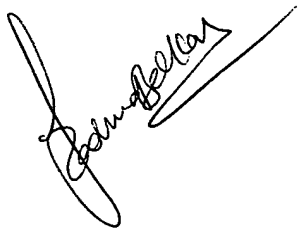
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

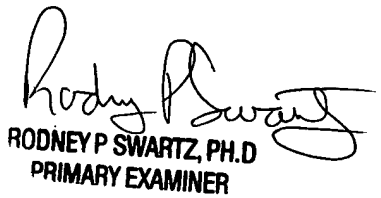
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

4/17/01





RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER